



JFW

## PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Steve A. Yon, et al.

Title: METHOD OF AMNUFACTURING A  
HEAT TRANSFER ELEMENT FOR  
INVIVO COOLING WOUT UNDERCUTS

Serial No.: 10/785,389

Examiner: Not Yet Known

Filed: February 24, 2004

Group Art 3739

Unit:

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

The following items are being submitted for this Information Disclosure Statement:

1.  Preliminary Statements
2.  FORM PTO - 1449

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on:

January 3, 2005  
(Date of Deposit)

Amanda L. Mineer  
(Name of the Person Making the Deposit)

Amanda L. Mineer  
(Signature)

January 4, 2005  
(Date of Signature)

## 1. Preliminary Statements

Applicants cite herewith patents, publications or other information of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR 1.56.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made, an admission that the information cited is, or is considered to be, material to patentability or that no other material information exists.

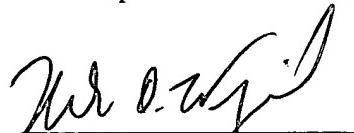
The filing of this information disclosure statement shall not be construed as an admission against interest in any manner.

No fee is believed to be due in connection with this submission as this Information Disclosure Statement is being filed within three (3) months of the application filing date or before receipt of the First Office Action.

However, if any fees are required in connection with this paper, authorization is hereby given to the Commissioner for Patents to charge same to Deposit Account No. 50-0914.

Date:

Jan. 4, 2005



Mark D. Wieczorek  
Attorney for Applicants  
Registration No. 37,966

Innercool Therapies, Inc.  
3931 Sorrento Valley Blvd.  
San Diego, CA 92121  
Phone: (858) 677-6390  
Fax: (858) 677-6391

Under the Paperwork Reduction Act of 1995, no persons are required to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

SEARCHED

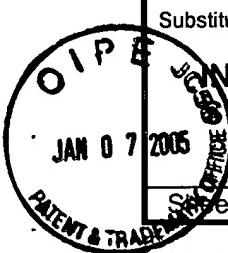
1

of

3

**Complete if Known**

|                        |                       |
|------------------------|-----------------------|
| Application Number     | 10/785,389            |
| Filing Date            | February 24, 2004     |
| First Named Inventor   | Stephen A. Yon et al. |
| Group Art Unit         | 3739                  |
| Examiner Name          | Not Yet Known         |
| Attorney Docket Number | 136001                |

**U.S. PATENT DOCUMENTS**

| Examiner Initials' | Cite No. <sup>1</sup> | U.S. Patent Document |                                   | Name of Patentee or Applicant of Cited Document | Date of Publications of Cited document MM-DD-YYYY | Pages, Column, Lines, Where Relevant Passages or Relevant Figures Appear |
|--------------------|-----------------------|----------------------|-----------------------------------|---|---|--|
|                    |                       | Number               | Kind Code <sup>2</sup> (if known) |   |   |  |
| AA                 | Re. 31,873            |                      |                                   | Howes   | 04/30/85  |  |
| AB                 | 2,077,453             |                      |                                   | Albright  | 04/20/37  |  |
| AC                 | 2,374,609             |                      |                                   | McCollum  | 04/24/45  |  |
| AD                 | 2,615,686             |                      |                                   | Davidson  | 10/28/52  |  |
| AE                 | 2,672,032             |                      |                                   | Towse   | 03/16/54  |  |
| AF                 | 2,913,009             |                      |                                   | Kuthe   | 11/17/59  |  |
| AG                 | 3,087,493             |                      |                                   | Schossow  | 04/30/63  |  |
| AH                 | 3,425,419             |                      |                                   | A.A. Dato                                       | 02/04/69  |  |
| AI                 | 3,504,674             |                      |                                   | Swenson et al.                                  | 04/07/70  |  |
| AJ                 | 3,612,175             |                      |                                   | Ford et al.                                     | 10/12/71  |  |
| AK                 | 4,038,519             |                      |                                   | Foucras   | 07/26/77  |  |
| AL                 | 4,072,146             |                      |                                   | Howes   | 02/07/78  |  |
| AM                 | 4,111,209             |                      |                                   | Wolvek et al                                    | 09/05/78  |  |
| AN                 | 4,497,890             |                      |                                   | Helbert   | 02/05/85  |  |
| AO                 | 4,762,130             |                      |                                   | Fogarty et al.                                  | 08/09/88  |  |
| AP                 | 4,781,799             |                      |                                   | Helbert et al.                                  | 11/01/88  |  |
| AQ                 | 4,863,442             |                      |                                   | DeMello et al                                   | 09/05/89  |  |
| AR                 | 4,964,409             |                      |                                   | Tramulis  | 10/23/90  |  |
| AS                 | 4,973,493             |                      |                                   | Guire   | 11/27/90  |  |
| AT                 | 4,979,959             |                      |                                   | Guire   | 12/25/90  |  |
| AU                 | 5,112,438             |                      |                                   | Bowers  | 05/12/92  |  |
| AV                 | 5,188,602             |                      |                                   | Nichols   | 02/23/93  |  |
| AW                 | 5,190,539             |                      |                                   | Fletcher et al.                                 | 03/02/93  |  |
| AX                 | 5,365,750             |                      |                                   | Greenthal                                       | 11/22/94  |  |
| AY                 | 5,617,854             |                      |                                   | Munsif  | 04/08/97  |  |
| AZ                 | 5,713,848             |                      |                                   | Dubrul et al                                    | 02/03/98  |  |
| BA                 | 5,861,021             |                      |                                   | Thome et al                                     | 01/19/99  |  |
| BB                 | 5,873,835             |                      |                                   | Hastings et al.                                 | 02/23/99  |  |
| BC                 | 5,899,898             |                      |                                   | Arless et al.                                   | 05/04/99  |  |
| BD                 | 5,899,899             |                      |                                   | Arless et al.                                   | 05/04/99  |  |
| BE                 | 5,957,963             |                      |                                   | Dobak III                                       | 09/28/99  |  |
| BF                 | 6,033,383             |                      |                                   | Ginsburg  | 03/07/00  |  |
| BG                 | 6,096,068             |                      |                                   | Dobak, III et al.                               | 08/01/00  |  |
| BH                 | 6,113,626             |                      |                                   | Clifton et al                                   | 09/05/00  |  |
| BI                 | 6,126,684             |                      |                                   | Gobin et al.                                    | 10/03/00  |  |
| BJ                 | 6,146,814             |                      |                                   | Millet  | 11/14/00  |  |
| BK                 | 6,149,673             |                      |                                   | Ginsburg  | 11/21/00  |  |
| BL                 | 6,165,207             |                      |                                   | Balding et al.                                  | 12/26/00  |  |

|                    |                 |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>12</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box ^ +

PTO/SB/O8B (10-96)

Approved for use through 10/31/99, OMB 0651-0031

Patent and Trademark Office: U.S./DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

Complete if Known

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

2

of

3

Application Number 10/785,389

Filing Date February 24, 2004

First Named Inventor Stephen A. Yon et al.

Group Art Unit 3739

Examiner Name Not Yet Known

Attorney Docket Number 136001

| Examiner Initials' | Cite No. <sup>1</sup> | U.S. Patent Document |                                   | Name of Patentee or Applicant of Cited Document | Date of Publications of Cited document MM-DD-YYYY | Pages, Column, Lines, Where Relevant Passages or Relevant Figures Appear |
|--------------------|-----------------------|----------------------|-----------------------------------|---|---|--|
|                    |                       | Number               | Kind Code <sup>2</sup> (if known) |   |   |  |
| BM                 | 6,231,594             | Dae                  |                                   | 05/15/01  |   |  |
| BN                 | 6,264,679             | Keller, et al.       |                                   | 07/24/01  |   |  |
| BO                 | 6,287,326             | Pecor                |                                   | 09/11/01  |   |  |
| BP                 | 6,436,071             | Schwartz             |                                   | 08/20/02  |   |  |
| BQ                 | 6,464,716             | Dobak III et al.     |                                   | 10/15/02  |   |  |
| BR                 | 6,520,933             | Evans et al.         |                                   | 02/18/03  |   |  |
| BS                 | 20020007203           | Gilmartin et al.     |                                   | 01/17/02  |   |  |
| BT                 | 20020016621           | Werneth et al.       |                                   | 02/07/02  |   |  |
| BU                 | 20020068964           | Dobak et al.         |                                   | 06/06/02  |   |  |
| BV                 | 20020072759           | Fry                  |                                   | 06/13/02  |   |  |
| BW                 | 20020116039           | Walker et al.        |                                   | 08/22/02  |   |  |
| BX                 | 20020183815           | Van Nest et al.      |                                   | 12/05/02  |   |  |
| BY                 | 20030014094           | Hammack              |                                   | 01/16/03  |   |  |
| BZ                 | 20030040782           | Walker et al.        |                                   | 02/27/03  |   |  |

**U.S. PATENT DOCUMENTS**

| Examiner Initials' | Cite No. <sup>1</sup> | Foreign Patent Document |                     |                                   | Name of Patentee or Applicant of Cited Document | Date of Publications of Cited document MM-DD-YYYY | Pages, Column, Lines, Where Relevant Passages or Relevant Figures Appear | T <sup>3</sup> |
|--------------------|-----------------------|-------------------------|---------------------|-----------------------------------|---|---|--|----------------|
|                    |                       | Office <sup>3</sup>     | Number <sup>4</sup> | Kind Code <sup>5</sup> (if known) |   |   |  |                |
| CA                 |                       | WO 99/48449             |                     |                                   | Del Mar Medical                                 | 09/30/99  |  |                |
| CB                 |                       | WO 99/66970             |                     |                                   | Del Mar Medical                                 | 12/29/99  |  |                |
| CC                 |                       | WO 01/08580             |                     |                                   | Alsius  | 02/08/01  |  |                |
| CD                 |                       | WO 01/13782             |                     |                                   | Cryogen   | 03/01/01  |  |                |
| CE                 |                       | WO 01/13809             |                     |                                   | Radiant Medical                                 | 03/01/01  |  |                |
| CF                 |                       | WO 01/13837             |                     |                                   | Innercool                                       | 03/01/01  |  |                |
| CG                 |                       | WO 02/36180             |                     |                                   | Alsius  | 05/10/02  |  |                |

**OTHER PRIOR ART—NON-PATENT LITERATURE DOCUMENTS**

|                    |                       |   |                |
|--------------------|-----------------------|---|----------------|
| Examiner Initials' | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|                    | CH                    | Behmann, F.W., et al.; « Heat Generation Control during Artificial Hypothermia: I: Experimental Examination of the Influence of Anesthetic Depth"; Pflügers Archiv, Bd. 266, S. 408-421 (1958) (German article with English translation)                        |                |
|                    | CI                    | Behmann, F.W., et al.; Intravascular Cooling, a Method to Achieve Controllable Hypothermia; Pflügers Archive, Vol. 263, pages 145-165 (1956) (German article with English translation)  |                |

|                    |                 |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>12</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to a collection of information unless it contains a valid OMB control number.

|   |   |    |   |                        |                       |
|---|---|----|---|------------------------|-----------------------|
| Substitute for form 1449B/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br><i>(use as many sheets as necessary)</i> |   |    |   | Complete if Known      |                       |
| Sheet   | 3 | of | 3 | Application Number     | 10/785,389            |
|   |   |    |   | Filing Date            | February 24, 2004     |
|   |   |    |   | First Named Inventor   | Stephen A. Yon et al. |
|   |   |    |   | Group Art Unit         | 3739                  |
|   |   |    |   | Examiner Name          | Not Yet Known         |
|   |   |    |   | Attorney Docket Number | 136001                |

| <b>OTHER PRIOR ART—NON-PATENT LITERATURE DOCUMENTS</b> |                       |   |  |                |
|--|-----------------------|---|--|----------------|
| Examiner Initials <sup>1</sup>                         | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |  | T <sup>2</sup> |
|  | CJ                    | Behmann, F.W.; "Regulation of heat production in experimental hypothermia of homothermal animals"; Naunyn Schmiedebergs Arch Exp Pathol Pharmakol; 228 (1-2): 126-128 (1956). (German article with English translation)   |  |                |
|  | CK                    | Behmann, F.W.; "Heat Generation Control during Artificial Hypothermia, an article about the economic problem of trembling stages"; Pflügers Archive, Vol. 263, pages 166-187 (1956) (German article with English translation)                                   |  |                |
|  | CL                    | Behmann, F.W.; "Heat Generation Control during Artificial Hypothermia: II. Theoretical Examinations"; Pflügers Archiv, Bd. 266, S. 422-446 (1958) (German article with English translation)   |  |                |
|  | CM                    | De Witte, Jan L., et al.; "Tramadol Reduces the Sweating, Vasoconstriction, and Shivering Thresholds"; Anesth Analg; Volume 87; Pages 173-179 (1998).   |  |                |
|  | CN                    | Hederer, G., et al.; "Animal Experiment Observations Regarding Cardiac Surgery under Intravascular Hypothermia"; Labgebbecjs Arch. U. Dtsch. A. Chir., Bd. 283, S. 601-625 (1957) (German article with English translation)                                     |  |                |
|  | CO                    | Jackson, Donald, et al; "Hypothermia : IV. Study of Hypothermia Induction Time with Various Pharmacological Agents (24617)"; Proc Soc Exp Biol Med.; 100(2): 332-335 (February 1959)  |  |                |
|  | CP                    | Mokhtarani, Masoud, et al.; "Buspirone and Meperidine Synergistically Reduce the Shivering Threshold; Anesth Analg; Volume 93; Pages 1233-1239 (2001).  |  |                |
|  | CQ                    | Piper, S.N., et al.; "Nefopam and Clonidine in the Prevention of Postanaesthetic Shivering"; Anaesthesia; Volume 54; Pages 695-699 (1999).  |  |                |
|  | CR                    | Sharkey, A., et al., "Inhibition of Postanesthetic Shivering with Radiant Heat", 1987   |  |                |
|  | CS                    | Wheelahan, Jennifer M., et al.; "Epidural Fentanyl Reduces the Shivering Threshold During Epidural Lidocaine Anesthesia"; Anesth Analg; Volume 87; Pages 587-590 (1998).  |  |                |
|  | CT                    | Zweifler et al, "Thermoregulatory vasoconstriction and shivering impede therapeutic hypothermia in acute ischemic stroke patients", 1996  |  |                |

|                    |                 |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>12</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.